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DAVID DANIEL CLARKE
DELEGATE OF COMMISSIONER OF PATENTS

AUSTRALIA

Patents Act 1990

GEOFFREY H WHITE
WEIYUN YU

PROVISIONAL SPECIFICATION

Invention Title:

Intraluminal Graft

The invention is described in the following statement:

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The present invention relates to an intraluminal graft for use in treatment of aneurysms or occlusive diseases.

It is known to use stents and intraluminal grafts of various designs for the treatment of aneurysms such as aortal aneurysms and for the treatment of occlusive diseases such as the occlusion of blood vessels or like ducts such as the bile duct and the ureter (which are all hereinafter called "vessels"). It is known to form such an intraluminal graft of a sleeve in which is disposed a plurality of self expanding wire stents (see Balko A. et al., "Transfemoral Placement of Intraluminal Polyurethane Prosthesis for Abdominal Aortic Aneurysms", Journal of Surgical Research 40, 305-309 (1986); Mirich D. et al, "Percutaneously Placed Endovascular Grafts for Aortic Aneurysms: Feasibility Study" Radiology, Vol. 170, No. 3, part 2, 1033-1037 (1989)). Such intraluminal grafts are inserted through the femoral artery into the aorta in a catheter. Upon the release of the graft from the catheter it expands to the size of the aorta above and below the aneurysms and bridges the aneurysms.

There are a number of problems associated with such known grafts. These include the problem of twisting or kinking of the graft when it has to extend along a non-linear path which, twisting or kinking can lead to occlusion of the lumen of the graft; lack of precise control of the expansion of the graft in the lumen; avoidance of inadvertent separation of a supporting stent and the covering sleeve; and maintaining the graft against longitudinal movement along the lumen in which it is placed. The present invention is directed to an alternative form of intraluminal graft which provides an alternative to the known grafts.

In a first aspect the present invention consists in an intraluminal graft comprising a tubular graft body

which is circumferentially reinforced along its length by a plurality of separate, spaced-apart, maleable wires, each of which has a generally closed sinusoidal or zig-zag shape, one of the wires being located adjacent to one end of the graft body such that alternate crests or apices of the wire projects beyond that end, the one wire having a greater amplitude and smaller wavelength than at least a majority of the other wires in the graft.

In another aspect the invention relates to a method for positioning an intraluminal graft as defined above comprising introducing a catheter into a vein, artery or other vessel in the body, causing an intraluminal graft as defined above to be carried through the catheter on an inflatable balloon until the graft extends into the vessel from the proximal end of the catheter, inflating the balloon to cause the alternate crests or apices of the one wire to be urged into contact with the wall of the vessel, deflating the balloon and withdrawing the balloon and the catheter from the vessel.

In preferred embodiments of the invention each end of the graft will be provided with a wire which has alternate crests or apices extending beyond the adjacent end of graft body. In each case this wire will have a greater amplitude and a small wavelength than the intermediate wires. The provision of the end wires having a greater amplitude and shorter wavelength than the intermediate wires keeps the flexibility of the graft at a maximum determined by the material from which the graft body is formed; it keeps the metal surface in contact with the blood to a minimum; it provides maximum resistance to compression in the middle of the graft; and it allows the end wires to protrude beyond the end of the tubular graft body. While the graft will normally have wires at each end of the graft with their crests extending beyond the graft body it may be necessary or desirable for a surgeon

to shorten a graft and this may be achieved by cutting off part of the graft body. In this case the graft will have extending crests at only one end.

The projection of alternate crests or apices of the end wire or wires beyond the end or ends of the graft body is an important feature of this invention. As the graft is expanded by a balloon the expansion of the wires, and of the balloon, will be limited by the diameter of the tubular graft body except in the region of the alternate crests or apices of the end wire or wires. The balloon will be able to expand these crests slightly more than the remainder of the wire so that they bell outwardly away from the adjacent end of the graft body. The crests are forced into contact with the wall of the vessel and thereby become at least partly embedded into the vessel wall. This belling out of the crests of the wires at one or both ends of the graft body into contact with the inside surface of the vessel wall and then being at least partly embedded in the wall will assist in resisting any tendency for the graft to move longitudinally within the vessel after insertion. The wire crests may extend across the lumen of a vessel opening into the vessel in which the graft is being placed without occluding that lumen. This allows the intraluminal graft to be used in situations in which the aneurysm to be bridged commences closely adjacent divergent blood vessels.

The tubular graft body is preferably formed of a thin biocompatible material such as Dacron or PTFE. The tube material is preferably crimped along its length to increase its flexibility, however, uncrimped material may be used in suitable circumstances. In preferred embodiments of the invention the graft body may be formed from a material having a limited amount of diametric elasticity to ensure that it can be expanded into contact with the vessel wall. The length and diameter of the

graft body will be determined by the individual circumstances of the application to which the intraluminal graft is to be put. Typically, the vessel will be assessed by X-ray or other similar examination and a suitably dimensioned graft selected for that application.

The wires are preferably formed of stainless steel or another metal or a plastic which is maleable and is biocompatible. Each wire is preferably woven into the fabric of the graft body to integrate the body and the reinforcing wires. This prevents any possibility of the wire reinforcement separating from the graft body during introduction of the graft or throughout its life. If the graft body is of a woven material the wires may be interwoven with the graft body during its production or alternatively they may be interwoven with the graft body after its manufacture. If the graft body was not woven but is knitted or of an impervious sheet material then the wires may be threaded through suitable holes formed in the graft body.

In alternative embodiments the wires may be held in place by sutures or adhesives or may be sandwiched between layers of a multi-layered tubular graft body. In all of the foregoing arrangements the wires are preferably disposed substantially within the graft body. It is, however, within the ambit of the invention that the wires may be connected to, and be disposed on, the outside surface of the graft body.

The intraluminal grafts according to this invention may be used to treat aneurysms or occlusive disease. In addition to treating aortic aneurysms they are particularly suitable for treating aneurysms of the femoral artery, the popliteal artery, the thoracic segment of the aorta, visceral arteries such as the renal and mesenteric arteries, the ileac artery and the sub-clavian artery. The presence of the metal wires in the

intraluminal grafts according to this invention assists in placing the graft as the wires are x-ray detectable. As the wires are arrayed along the length of the graft the complete position of the graft in the body can be continuously monitored.

The grafts according to this invention are typically substantially of constant diameter along their length ie, they are substantially cylindrical. It is possible, however, for the grafts to be frusto-conical in shape with a diameter that increases, or decreases, along the length of the graft.

The ends of the wires are joined together to form a tail which is preferably on the outside of the graft body and is positioned to lie along its radially outer surface. The ends may be joined by welding, by being twisted together or in any other suitable manner. The ends of the wires may inadvertently perforate the vessel in which the graft is placed, however, any such perforation will be occluded by the graft body thus ensuring that such a perforation will not adversely affect the patient. The ends of adjacent wires are preferably spaced apart radially about the graft body so as not to affect its flexibility and to avoid a line of ends engaging the wall of the vessel. The ends of adjacent wires preferably project in opposite directions along the vessel body. When the intraluminal graft is inserted into a vessel those wire ends which engage the inside surface of the vessel wall will assist in preventing the graft from inadvertent movement along the vessel. Causing the ends of alternate wires to project in opposite longitudinal directions along the graft body will assist in preventing longitudinal movement of the graft along the vessel in either direction.

Hereinafter given by way of example is a preferred embodiment of the present invention described with

reference to the accompanying drawings, in which:-

Fig. 1 is a diagrammatic partially cut-away ventral view of a patient with an aortic aneurysm which has been bridged by an intraluminal graft according to the present invention;

Fig. 2 is a side elevational view of the intraluminal graft of Fig. 1;

Fig. 3 is a longitudinal sectional view through the intraluminal graft of Fig. 2;

Fig. 4 is a detailed longitudinal sectional view through the intraluminal graft of Fig. 2 as it is being expanded into contact with the aorta of a patient during placement;

Fig. 5 is a detailed longitudinal sectional wire through the intraluminal graft of Fig. 2 after it has been inserted into the aorta of a patient;

Fig. 6 is a detailed elevational view of one end of the intraluminal graft of Fig. 2; and

Fig. 7 is a detailed perspective view of the one end of the intraluminal graft of Fig. 6 showing how the alternate crests of the end wire of the graft are pushed radially outwardly during insertion of the graft.

The intraluminal graft 10 is adapted for insertion transfemorally into a patient to achieve bridging and occlusion of the aneurysm present in the aorta. As is seen in Fig. 1 the aorta 11 is connected to the left right femoral arteries 12 and 13. The aortic aneurysm is located between the renal arteries 14 and 15 and the junctions of the femoral arterial 12 and 13 with the 11. The graft 10 is, as will be described subsequently in more detail, inserted inside a catheter introduced into one of the femoral arteries 12 or 13 in a leg of the patient. Once the catheter is located appropriately with its proximal end in the aorta 11 the graft 10 is ejected from the catheter and expanded so that each end is in

intimate contact around its full periphery with the aorta 11. The graft 10 then bridges the aneurysm and isolates any thrombosis or gelatinuous material associated with the aneurysm outside the graft 10 to reduce the risk of embolisation.

The intraluminal graft 10 comprises a crimped tube 16 of woven Dacron. The tube is reinforced along its length by a number of separate and spaced apart stainless-steel wires 17 (each of which has a generally closed sinusoidal shape). The wires 17 are preferably as thin as possible and are typically .3 to .4 mm in diameter. The wires 17 are maleable and may be bent into any desired shape, i.e. they are not resilient to any substantial extent so that they have to be physically expanded into contact with the aorta rather than expanding by virtue of their own resilience. The wires 17 are each woven into the fabric of the tube 16 such that alternate crests of each wire 17 are outside the tube 16 with the remainder of that wire 17 inside the tube (except in the case of the endmost wires as will be hereinafter described). The ends of each wire 17 are located outside the tube 16 and are twisted together to form a tail 18. The tails 18 of alternate wires 17 are bent to extend in opposite longitudinal directions along the outside surface of the tube 16.

The endmost ones of the wires 17 have a greater amplitude and a shorter wavelength than the intermediate wires 17. They also overhang the respective ends of the tube 17 so that alternate crests of those wires extend longitudinally beyond the end of the tube 16.

In use the graft 10 is radially compressed about an inflation balloon 19 (see Fig. 4) and the assembly is inserted into the end of a sheath catheter 21. The sheath catheter 21 is inserted in a known manner through the femoral artery into the aorta 11 until the proximal end of the catheter 21 is beyond the proximal end of the

aneurysm. The balloon 19 and the collapsed graft 10 disposed on it, are held stationary and the catheter withdrawn until the graft 10 is fully exposed and spans the aneurysm. The balloon is then inflated to expand the graft 10. The diameter of the tube 16 determines the maximum expansions of the majority of the graft 10 and this diameter has been selected in advance by X-ray examination, or the like, to be substantially equal or only very slightly larger than, the diameter of the undistended aorta 11. The balloon is, however, able to expand the alternating crests of the end wires 17 so that they are pushed firmly into contact with the wall of the aorta. These radially outwardly displaced crests serve to more effectively restrain the graft 10 against longitudinal movement relative to the aorta.

It will be appreciated by persons skilled in the art that numerous variations and/or modifications may be made to the invention as shown in the specific embodiments without departing from the spirit or scope of the invention as broadly described. The present embodiments are, therefore, to be considered in all respects as illustrative and not restrictive.

DATED this day of

GEOFFREY H WHITE & WEIY[illegible]
Patent Attorneys for the
Applicants:

F.B. RICE & CO.

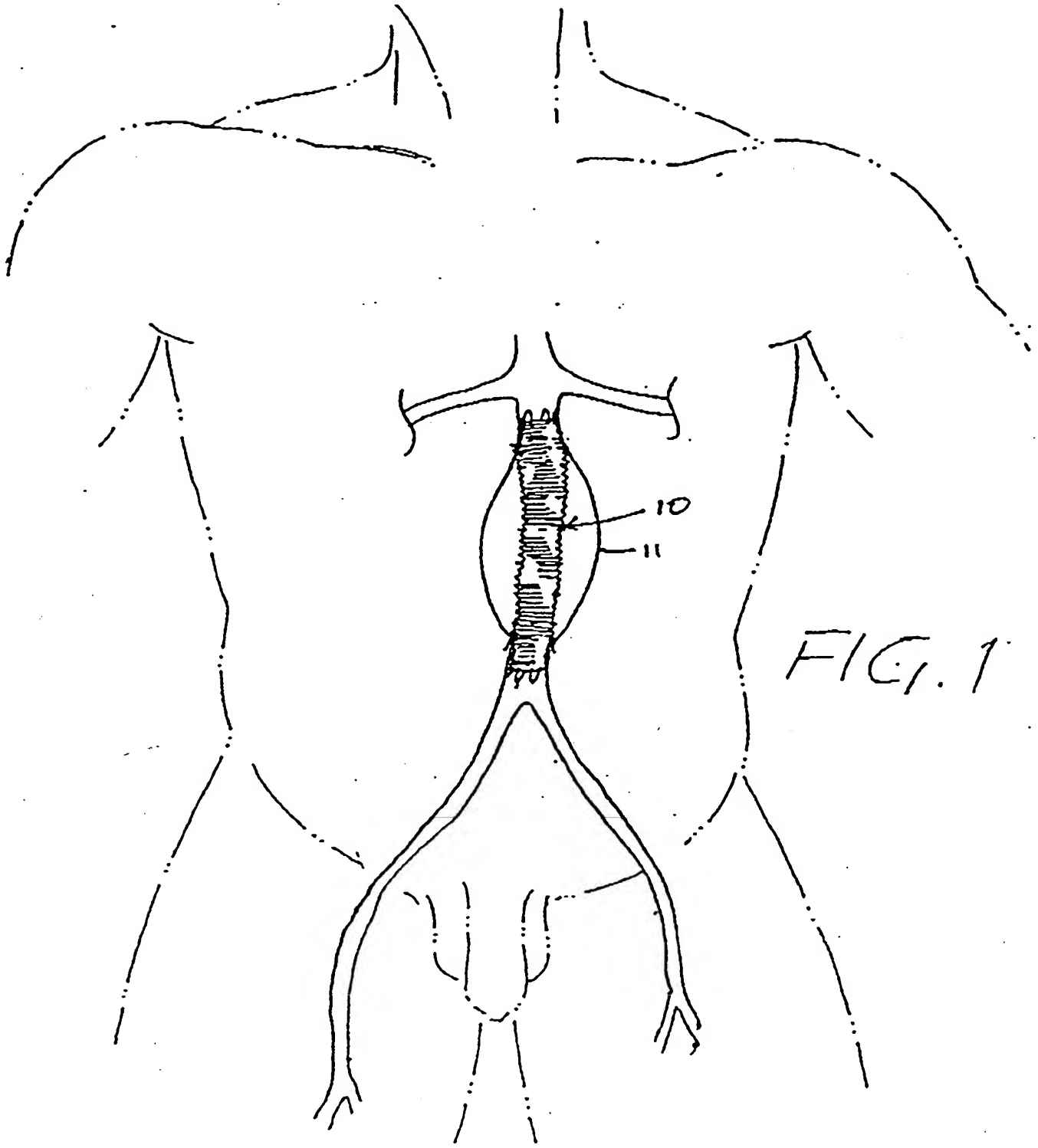


FIG. 1

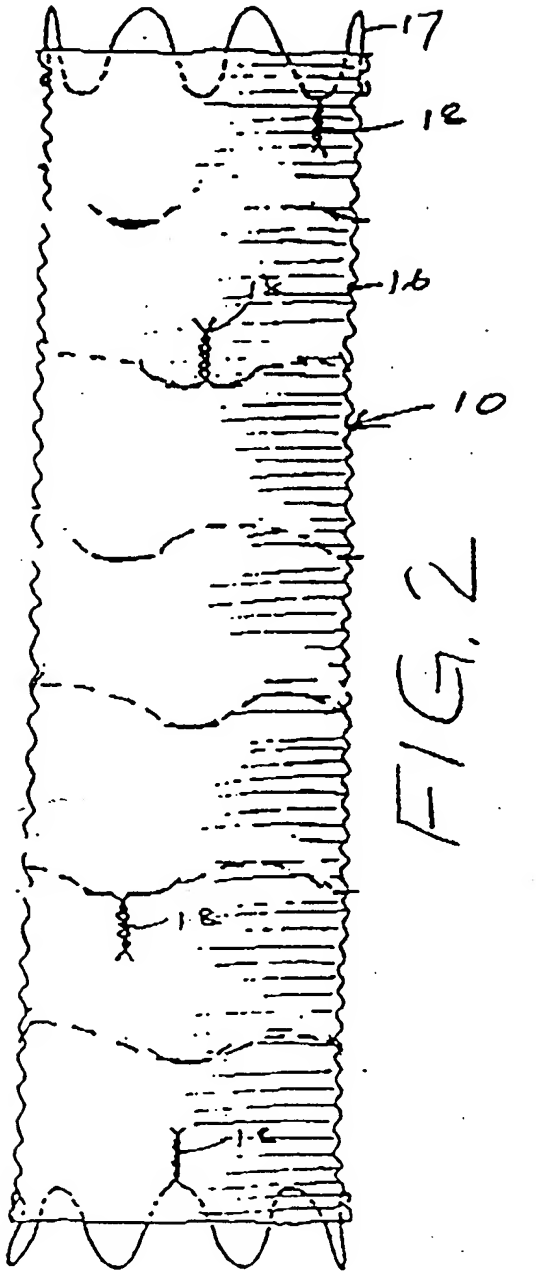


FIG. 2

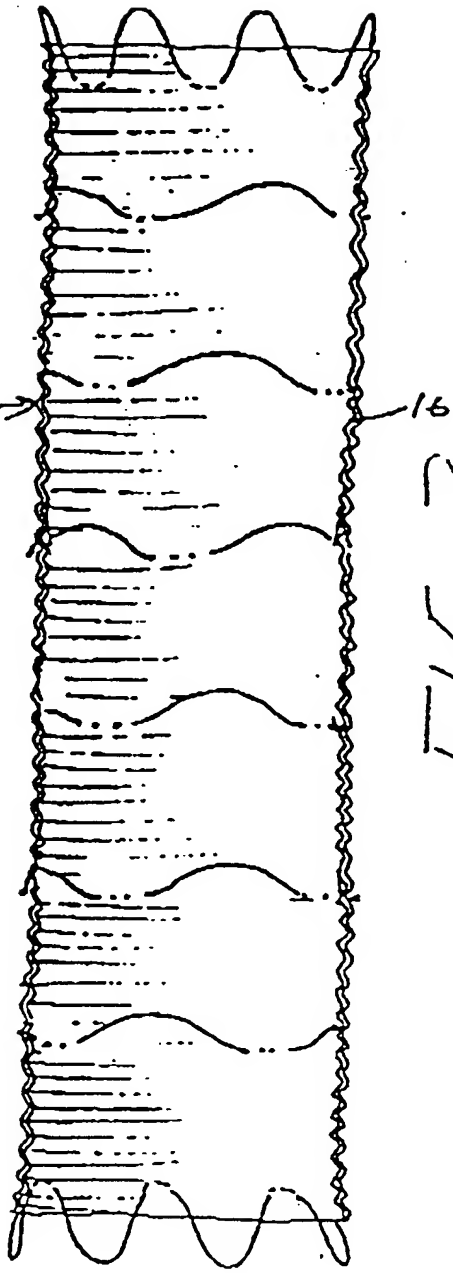


FIG. 3

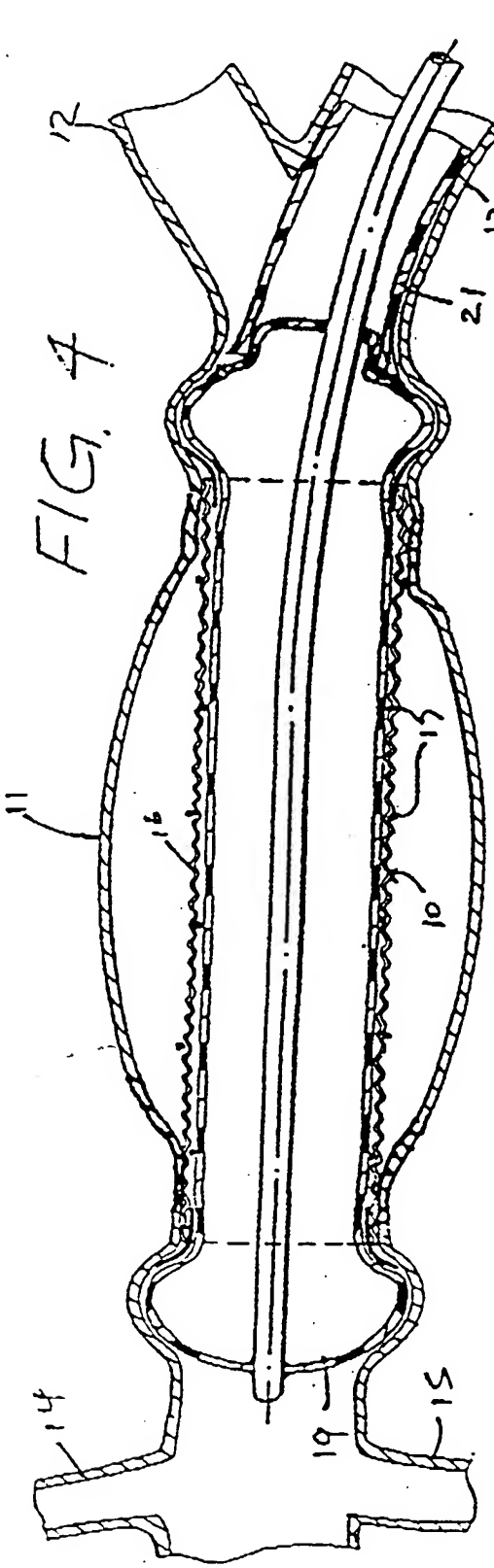


FIG. 4

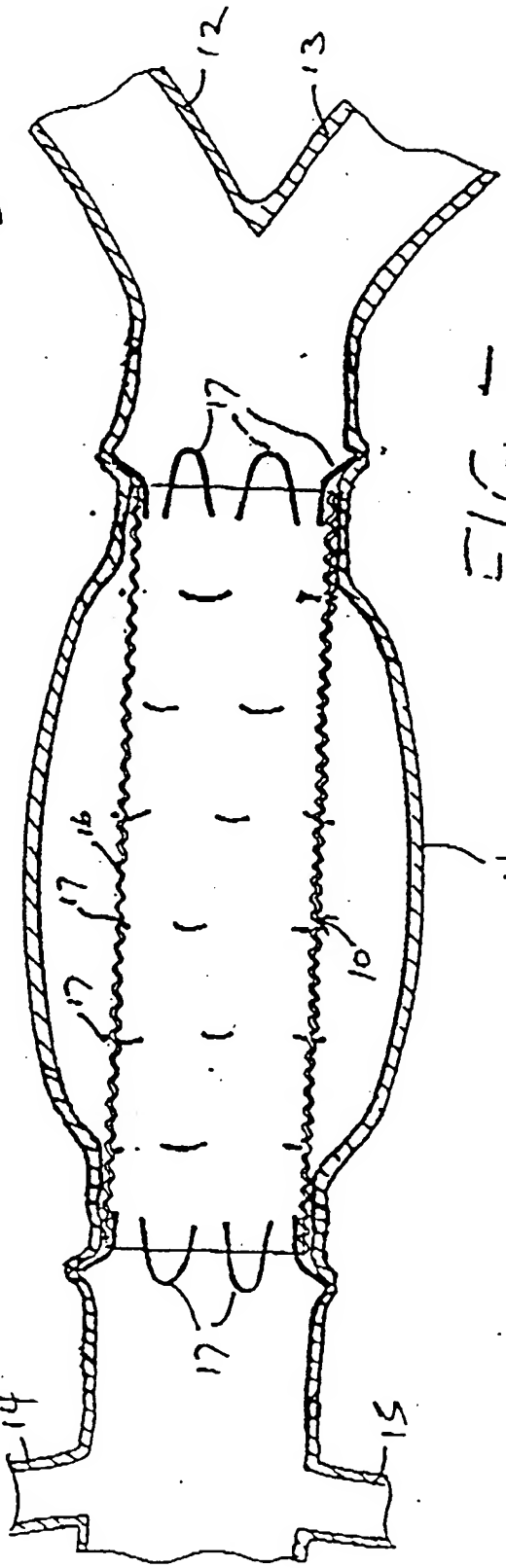


FIG. 5

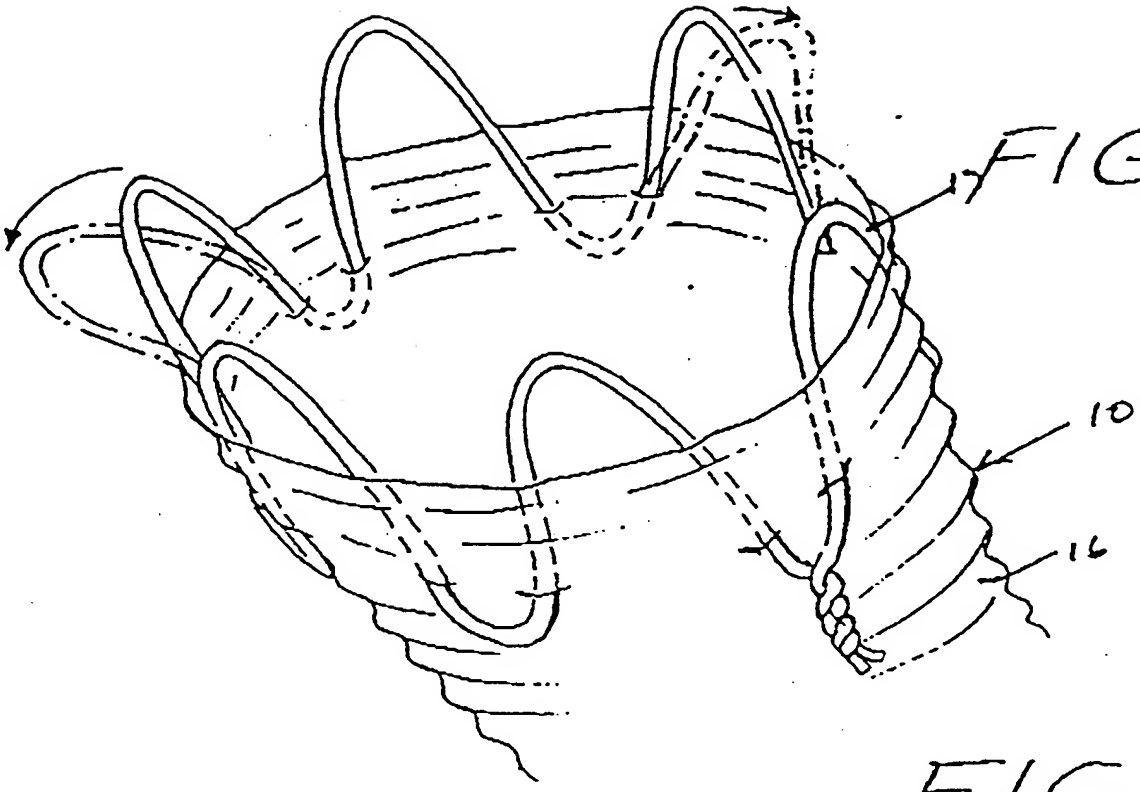
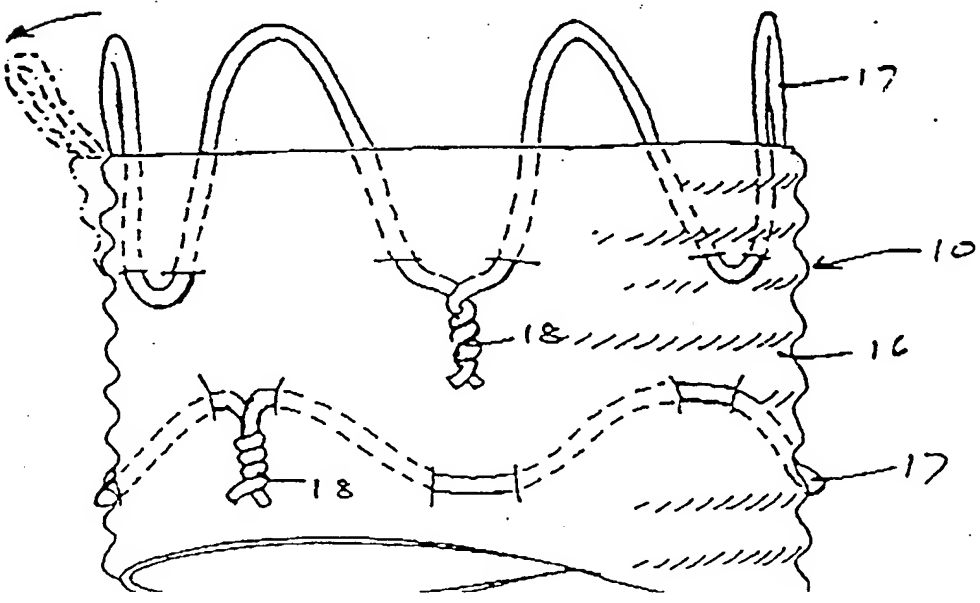


FIG. 7

FIG. 6



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